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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/072,177 | 02/11/2002 | Robert E. Fischell | APJOHN-10207 | 1327 |

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| EXAMINER | |
|---|---|
| SHARAREH, SHAHNAM J | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1617 | |

DATE MAILED: 03/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/072,177 | FISCHELL ET AL. | |
| | Examiner | Art Unit | |
| | Shahnam Sharareh | 1617 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *17 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *5-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

***Continued Examination***

1. Applicant's election without traverse of Group I, claims 1-4 and the species sirolimus in the reply filed on November 17, 2005 is acknowledged. Claims 5-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on November 17, 2005. Accordingly, Examination on the merits of claims continues to the extent they read on the elected species.

2. For the sake of brevity, Examiner notes that there were two elections made in response to Examiner's requirement. The first was filed on November 17, 2005 by Mr. Thomas Howerton, the attorney of record. Accordingly, Group I was elected for further prosecution on their merits. The second was filed on January 01, 2006 by Mr. Robert Fischell, the inventor, who elected Group II for further prosecution. Since there was an inconsistency on the election, Examiner contacted Mr. Howerton on February 21, 2006 for further clarification. (see Attached Interview Summary). Accordingly, Examination on the merits of claims 1-4 is hereby continued.

3. This application contains claim 5-22 are drawn to an invention nonelected. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

***Priority***

4. In order to receive the benefit of an earlier filing Applicant must first convey the inventive concept of the claim as a whole consistent with the requirements of the 35

USC § 112 first paragraph. The second application (which is called a continuing application) must be an application for a patent for an invention which is also disclosed in the first application (the parent or provisional application); the disclosure of the invention in the parent application and in the continuing application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See In re Albrecht, 168 USPQ 293 (CCPA 1971).

35 USC § 112 first paragraph states:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Accordingly, the specification must describe in the invention in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Here, Applicant has not complied with the conditions for receiving the benefit of an earlier filing date because the entire scope of the instant claims have not been disclosed in earlier applications.

5. Applicant is informed that under 35 USC §112, first paragraph, the requirement for "written description of the invention" is separate and distinct from the requirement for enablement. The purpose of the "written description" requirement is broader than to merely explain how to "make and use" or simply disclose an element of a claimed invention; rather, the applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. MPEP 2163.05 (I). Although one might not have to describe exactly the subject matter

claimed, the description must clearly allow persons of ordinary skill in the art to recognize that the inventor invented what is claimed. In re Gosteli, 872 F.2d 1008, 1012,10 USPQ2d 1614, 1618 (Fed. Cir. 1989), MEPE 2163.02.

6. Thus, the test for sufficiency of support in a parent application is whether the disclosure of the application relied upon, "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." Ralston Purina Co. v. Far-Mar-Co, Inc., 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (quoting In re Kaslow, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983)). In the instant case, the possession of the invention as a whole is assessed based on the combined elements of the instantly claimed surgical wrap sheet including individual the combination of suitable sheet material, antiproliferative drugs and further an additional medication within the scope of the instant claim 4. Since Applicant has not disclosed the entire scope of the instant pending claims in any of the parent cases, the written description requirements are not met.

7. Further, "specific claims to single compounds require reasonably specific supporting disclosure; while naming is not essential, something more than disclosure of class ... is required; given time, a chemist could name all of the half million compounds within scope of broadest claim, which claims is supported by broad disclosure, this does not constitute support for each compound individually when separately claimed." In re Ruschig, 154 USPQ 118, CCPA 1967. Examiner adds "entitlement to a filing date does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed. It extends only to that which is disclosed. Lockwood v. American

Airlines Inc., 107 F3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed Cir. 1997). Accordingly, species within a genus must be sufficiently disclosed in the parent cases to the extend that one of ordinary skill in the art would interpret that Applicant was in possession of the claimed species at the time of filing of the parent applications.

8. In reviewing the chain of priority of the instant application, Examiner takes the position that even though some of the prior applications refer to biodegradable sheets comprising sirolimus (rapamycin), they do not disclosed specific surgical wrap sheets containing such anti-proliferatives as antisense to c-myc, or any functional analog of sirolimus alone or even combination of said agents with one additional medication as recited in the instant claim 4. The first disclosure of the term "anti-sense to c-myc and any functional analogs of sirolimus" appear to be in this application filed on February 11, 2002.

9. The specific combination of a wrap sheet of material adapted for being wrapped generally around tissue of human body and c-myc, or any functional analogs of sirolimus, with or without an additional medication does not appear in any of the parent applications. Thus, the effective priority date of said composition is the filing date of the instant application, February 11, 2002.

10. However, Examiner adds that Application SN 09/772,693 appear to recite the use of some of sirolimus analogs, which is narrower than the scope of the instant claims. However, neither any functional analogs nor their combination with antibiotic, anti-inflammatory or analgesics in a surgical wrap sheet have been described in the earlier applications.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

12. Claim 1 recites the limitations "material adapted for being wrapped generally around tissues of a human body." Such language is ambiguous because it appears relative in nature. The term "generally" in claim 1 is a relative term which renders the claim indefinite. The term "generally" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

13. Claim 1 and 4 uses the transitional phrase "being selected from the group that includes." Such transitional phrase renders the scope of the claim ambiguous, because it appears to be an improper Markush language. Please note that the transitional phrase "include" is construed as comprising. Applicant is encouraged to use proper Markush language. Alternative expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. When materials recited in a claim are so related as to constitute a proper Markush group, they may be recited in the conventional manner, or alternatively. For example, if "wherein R is a material selected from the group consisting of A, B, C and D" is a proper limitation, then "wherein R is A, B, C or D" shall also be considered proper. See MPEP 2173.

14. The recitation of "any functional analog of sirolimus including" is ambiguous. First, the specification does not describe what is meant by or is the scope of the term "any functional analog."

Second, the use of "including" in this case creates the improper use of a broad range with a narrow range in the same claim. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

In the present instance, claim 1 recites the broad recitation "any functional analog of sirolimus," and the claim also recites "including SDZ-RAD, etc ....." which is the narrower statement of the limitation "any functional analog of sirolimus." Correction is requested

15. The recitation of "...32-dethoxy, 2-desmethyl and proline" in claim 1 is ambiguous. Where applicant acts as his or her own lexicographer to specifically define

a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term "32-demethoxy, 2-desmethyl and proline" in claim 1 is used by the claim to mean "any functional analog of sirolimus." However, 32-demethoxy, 2-demethyl are functional groups not related to sirolimus and proline is a compound not related to sirolimus. These terms are indefinite because the specification does not clearly redefine the term.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

16. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Morris et al US Patent 5,563,146.

The instant claims are directed to a sheet comprising a material suitable as surgical wrap and sirolimus (rapamycin). Examiner also states the scope of claim 4 is not limited to the enumerated limitations, because the transitional phrase employed does not exclude the use of any additional medication.

Morris discloses methods treating restenosis comprising administering rapamycin transdermally alone or in combination with additional medication such as mycophenolic acid. (col 4, lines 7-33; col 12, lines 26-35; col 11, lines 5-23). Morris teaches transdermal patches and occlusive devices containing rapamycin (see col 11, lines 10-25). Morris explicitly claims administration of rapamycin transdermally or via vascular stent impregnated with rapamycin (col 12, lines 32-35). Examiner views such delivery systems as transdermal patches or stent to fall within the instant limitation "material adapted for being wrapped generally around tissue of a human body." Accordingly, Morris anticipates the limitations of the instant claims.

17. Claims 1-3 are rejected under 35 U.S.C. 102(e) as being anticipated by Wright et al US Patent 6,273,913.

Wright teaches local delivery of rapamycin from micropores in the body of a stent or a polymer coating applied on a stent. (see abstract, col 6-8). Wright specifically teaches polymeric sheets that can be wrapped around tissues of a human body (see col 7, lines 5-26). Thus, Wright anticipates the limitations of the instant claims.

18. Claims 1-4 are rejected under 35 U.S.C. 102(e) as being anticipated by Iyer et al US Patent 6,726,923.

Iyer describes a drug-eluting biodegradable matrix comprising rapamycin for treating anastomosis. (see col 18-22). The matrix of Iyer is capable of being wrapped around tissues of a human body, because it is perivasularly wrapped around site of interest. The matrix of Iyer is biodegradable and stable (see col 4, lines 10-col 5, line 40). Iyer encourages the use of other anti-inflammatory such as dexamethasone with rapamycin. (col 6, lines 55-67). Accordingly, Iyer anticipates the limitations of the instant claims.

***Claim Rejections - 35 USC § 103***

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

19. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wright in view of Iyer .

The teachings of Wright are discussed above. Wirght fails to explicitly combine another anti-inflammatory agent with his rapamycin containing polymeric sheet.

Iyer clearly suggests the use of additional anti-inflammatory agents with rapamycin to potentiate the clinical benefits. .

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to add another beneficial medication such as dexametason of Iyer to the matrix system of Wright to improve the antiproliferative benefits of Wright's polymeric sheet. The ordinary skill in the art would have been motivated to do such modifications because as suggested by Iyer, the use of drugs such as dexametasone decreases vasoproliferative process (see Iyer, col 6, lines 60-65).

***Conclusion***

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh, JD, PharmD, whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The

fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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